Peri-procedural Safety of Left Atrial Appendage Occlusion with the WATCHMAN Device. Preliminary Data From the EWOLUTION Registry

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Objective: Left Atrial Appendage Occlusion (LAAO) with Watchman has been found effective and non-inferior to oral anticoagulation (OAC) in randomized trials and prospective registries in pts with Atrial Fibrillation. The prospective, multi-center EWOLUTION registry aims to obtain real world clinical data on procedural success and complications, as well as long-term pt outcomes, including bleeding and incidence of stroke and TIA. Pts will be followed for 2 yrs according to the schedule and standard practice at the enrolling centers.

Methods: 1025 pts scheduled for a WATCHMAN implant at 47 centers in 13 countries were prospectively enrolled over a time period of 19 months. Current ESC guidelines recommend LAA closure for pts with a (relative) contraindication for oral anticoagulation and increased risk of stroke. Here we report on periprocedural safety in this high-risk population.

Results: Baseline data found the population to present with higher CHADS2 (2.8±1.3), CHADSVASc (4.5±1.6) and HAS-BLED (2.3±1.2) scores in comparison to previous RCT like PROTECT-AF and PREVAIL (CHADS2 2.2 ± 1.2 and 2.6 ± 1.0, respectively). 59.9% were male, mean age was 73.5±8.9, 34.3% had congestive heart failure, 55.9% were NYHA Class II and 31.3% were NYHA Class III. 15.6% had abnormal renal function. 10.6% had a history of TIA, 19.8% had a history of ischemic stroke and 14.8% had previous hemorrhagic stroke. 31.3% had a history of major bleeding. The investigators deemed 60.9% of the pts to be (relatively) contraindicated for oral anticoagulation. 99.3% of procedures were successful in closing the LAA with no/minimal (<5mm) leakage assessed by peri-procedural transesophageal echo. Despite the high-risk population, 93.1% of patients were free from any adverse event within the first 30 days of the implant procedure. Most notably, pericardial effusion occurred only in 0.9% of the procedures. Device embolization was observed in only two cases (0.2%).

Conclusion: LAA closure with the Watchman device has a high initial success rate in complete LAA closure with minimal periprocedural risk in appropriately trained hands even in multi-morbid patients. Improvements in implantation techniques and operator experience may further improve the net clinical benefit of the procedure.

Disclosure: